AND 21 CFR) \$101.93 5 SEP 22 P2 23

SEP 1 3 2005

This notification is being filed on behalf of <u>New Chapter, Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend® PM**.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): Promotes a healthy inflammation response
- (Statement 2): Promotes healthy joint function and structural health.
- (Statement 3): A Supercritical New Chapter in Inflammation Modulation

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

Statement <u>Number</u>	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement		
1.	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian.		
2.	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian.		
3 .	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian.		

The following identifies the brand name of each supplement for which a statement is made:

Statement <u>Number</u>	Brand Name	Label or Labeling?
1.	Zyflamend® PM	Label and Labeling
2.	Zyflamend® PM	Label and Labeling
3.	Zyflamend® PM	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New
Chapter, Inc. I certify that the information presented and contained in this Notification is
complete and accurate, and that New Chapter, Inc. has substantiation that each
structure-function statement is truthful and not misleading.
Quantity on En Chapter Tostes DA administrat

[Name] [Title]

975 0162 LET 16693

05-6062

This notification is being filed on behalf of <u>New Chapter, Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend® PM**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): New Chapter's patented Zyflamend® PM formulation represents a scientific breakthrough in promoting a health inflammation response.

(Statement 2): Recent research studies suggest this may be an effective strategy to promote healthy joint function and normal cell growth.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

Statement <u>Number</u>	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement	
1.	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian.	
2.	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian	

The following identifies the brand name of each supplement for which a statement is made:

Statement <u>Number</u>	Brand Name	<u>Label or Labeling?</u>
1.	Zyflamend® PM	Label and Labeling
2.	Zyflamend® PM	Label and Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New Chapter, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that New Chapter, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date Signed Wyst 31, 200 5 By: That was a substantiation that each structure-function statement is truthful and not misleading.

[Title]

This notification is being filed on behalf of <u>New Chapter, Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend® PM**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): New Chapter has extensively researched the herbal pharmacopoeia and international medical databases and discovered that the following time-tested herbs, properly extracted and blended in the correct proportions, contain at least 8 phytonutrients that may safely and significantly promote a healthy inflammation response and gently and safely promote the experience of deep and satisfying sleep.

(Statement 2): Supercritical extract marked for humulones, potent inflammation modulators that also significantly promote structural health.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

Statement Number	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement	
1.	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian.	
2.	Hops	

The following identifies the brand name of each supplement for which a statement is made:

Statement <u>Number</u>	Brand Name	Label or Labeling?
1.	Zyflamend® PM	Label and Labeling
2.	Zyflamend® PM	Label and Labeling
		fy this Notification on behalf of <u>New</u>

<u>Chapter, Inc.</u> I certify that the information presented and contained in this Notification is complete and accurate, and that <u>New Chapter, Inc.</u> has substantiation that each structure-function statement is truthful and not misleading.

[Name [Title]

This notification is being filed on behalf of <u>New Chapter, Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend® PM**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Dual extracts *Potency Assured* ™ to include inflammation modulator apigenin. Traditionally used to support a natural state of deep restfulness.

(Statement 2): Contains the inflammation modulator ursolic acid, which significantly enhances detoxification and promotes a healthy inflammation response.

(Statement 3): Contains 11 inflammation modulating compounds according to USDA database. German Commission E, a leading authority on herbal medicine, prescribes Melissa for optimal sleep quality.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

Statement	Identity of Dietary Ingredient(s) or		
Number	Supplement(s) that is the subject of the Statement		
1.	Chamomile		
2.	Holy Basil (Ocimum sanctum)		
3.	Melissa		

The following identifies the brand name of each supplement for which a statement is made:

Statement <u>Number</u>	Brand Name	Label or Labeling?
1.	Zyflamend® PM	Label and Labeling
2.	Zyflamend® PM	Label and Labeling
3.	Zyflamend® PM	Label and Labeling

Chapter, Inc. I certify that the information presented and contained in this Notification is
complete and accurate, and that New Chapter, Inc. has substantiation that each
structure-function statement is truthful and not misleading.
Date Signed Myst31, 2005 By: Mystin Hoster, OA Administrator
Date Signed: USUST, 2000 By: 1910UIL TULLE, WH HOUNDED
[Name]
Title1

L Kristin Foster am authorized to certify this Notification on behalf of New

This notification is being filed on behalf of <u>New Chapter, Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend® PM**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Source of 14 inflammation modulating compounds according to USDA database. The journal of Pharmacopsychiatry concludes valerian offers multiple "improvements in sleep structure."

(Statement 2): Contains inflammation modulator baicalein, traditionally recognized for its calming influence.

(Statement 3): Supercritical extract modulates both eicosanoid cascades and offers numerous anti-aging constituents.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

Statement	Identity of Dietary Ingredient(s) or		
Number	Supplement(s) that is the subject of the Statement		
1.	Valerian		
2.	Baikal skullcap		
3.	Ginger		

The following identifies the brand name of each supplement for which a statement is made:

Statement <u>Number</u>	Brand Name	Label or Labeling?
1.	Zyflamend® PM	Label and Labeling
2.	Zyflamend® PM	Label and Labeling
3.	Zyflamend® PM	Label and Labeling

<u>Chapter, Inc.</u> I certify that the information presented and contained in this Notification is
complete and accurate, and that New Chapter, Inc. has substantiation that each
Date Signed My Statement is truthful and not misleading. Date Signed My Statement is truthful and not misleading. Date Signed My Statement is truthful and not misleading.
Aug 101 - Chuten South DNAdministrator
Date Signed My Motor By: POR By: POR MICHO SOURCE, WHO WILL WILL WILL SOURCE TO SOURCE AND A SIGNED SOURCE
[Name]
[Title]

I. Kristin Foster am authorized to certify this Notification on behalf of New

This notification is being filed on behalf of <u>New Chapter, Inc.</u> which is the <u>manufacturer</u> of the product(s) which bear the statements identified in this notification. Its business address is:

<u>22 High St. PO Box 1947, Brattleboro, VT 05302.</u> This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R §101.93. The dietary supplement product on whose label or labeling the statements appear is **Zyflamend® PM**.

The text of each structure-function statement for which notification is now being given is:

(Statement 1): Unique curcumin phytonutrient complex, synergistic with green tea, significantly multiplying each herb's ability to promote healthy eicosanoid balance.

(Statement 2): Promotes healthy cardiovascular function.

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

Statement Number	Identity of Dietary Ingredient(s) or Supplement(s) that is the subject of the Statement
1.	Turmeric
2.	Holy Basil, Turmeric, Baikal Skullcap, Melissa, Chamomile, Hops, Ginger and Valerian.

The following identifies the brand name of each supplement for which a statement is made:

Statement <u>Number</u>	Brand Name	Label or Labeling?
1.	Zyflamend® PM	Label and Labeling
2.	Zyflamend® PM	Labeling

I, Kristin Foster am authorized to certify this Notification on behalf of New
Chapter, Inc. I certify that the information presented and contained in this Notification is
complete and accurate, and that New Chapter, Inc. has substantiation that each
structure-function statement is truthful and not misleading,
Date Signed Myst 31, 200.5 By: Mrwtin Justice DA administrator
[Name]
[Title]